REMARKS/ARGUMENTS

This Amendment is submitted in response to the Office Action mailed January 22, 2010. At that time claims 1, 3-8, 10-24, 37, 39-42, 45-46, 48-50, 52-54 and 57 were pending in the application.

By this Amendment, claims 1, 7, and 24 have been amended. Exemplary support for the amendment to claims 1, 7, and 24 can be found in original claims 1, 7, and 24 and paragraphs [0046] and [0051] of the specification of corresponding U.S. Patent Publication No. 20050010138. No new matter has been added. Claims 37, 39, 41, 42, and 57 have been cancelled. Accordingly, claims 1, 3-8, 10-24, 40, 45-46, 48-50, and 52-54 are presented for reconsideration by the Examiner.

Claim Rejections under 35 U.S.C. § 112

Claims 5, 12, and 41 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Claim 41 has been cancelled. It is respectfully submitted that the amendments to claims 1 and 7 address the issues identified in the Office Action and that the rejections are now moot. Support for the amendments to claims 1 and 7 is found in paragraph [0046], which includes a description that "when the legs are constrained by the exterior conduit 130 they lay substantially flush with respect to one another . . ." It is further noted that flush, as an adjective, is defined as "immediately adjacent". *See Dictionary.com*.

Claim Rejections under 35 U.S.C. § 103

Claim 1

Claims 1 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,919,147 issued to Krishna Jain ("Jain") in view of U.S. Patent No. 5,010,892 issued to Colvin et al. ("Colvin"), U.S. Patent No. 6,712,771 issued to Haddock et al. ("Haddock"), U.S. Patent No. 6,033,359 issued to Yuzuru Doi ("Doi"), and U.S. Patent No. 6,450,997 issued to Rosalyn Baxter-Jones ("Baxter-Jones"). The Applicants respectfully traverses this rejection.

The Patent Office bears the burden of establishing a *prima facie* case of obviousness. M.P.E.P. § 2142 (8th ed., rev. 6). To meet this burden, the Patent Office must set forth an explicit analysis supporting an obviousness rejection. *Id.* In particular, "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.* If the evidence presented in the analysis does not meet the preponderance of evidence standard (i.e., the evidence fails to show that it is more likely than not that an obviousness rejection is proper), then the rejection fails to set forth a *prima facie* case of obviousness. *See id.*

The Applicants respectfully submit that the Office Action fails to set forth a *prima facie* case of obviousness with respect to amended claim 1 for at least the reasons that the articulated reasoning for modifying Jain with the teachings of Colvin, Haddock, Doi, and Baster-Jones fails to meet the preponderance of evidence standard.

Brief descriptions of Jain, Colvin, Haddock, Doi, and Baxter-Jones are set forth hereafter, followed by an analysis of the enumerated reasons that the Office Action is believed to have failed to provide a *prima facie* case of obviousness with respect to amended claim 1.

Jain

Jain discloses a device for measuring the intravascular diameter of an anotomical duct such as a blood vessel. *See* Jain, column 1, lines 11-14. As shown in FIG. 3 (reproduced below), an outward bias of the filaments 44 urges them to fan outwardly in a conical fashion, such that they will extend radially outwardly of the distal end 32 of the sheath 22. *See* column 3, lines 47-50. A surgeon then notes the axial distance that the proximal end 38 has moved inwardly with respect to the proximal end 30 of the sheath 22 by observing the graduated markings 42. *See* Jain, column 3, lines 58-61, FIG. 4 (reproduced below).

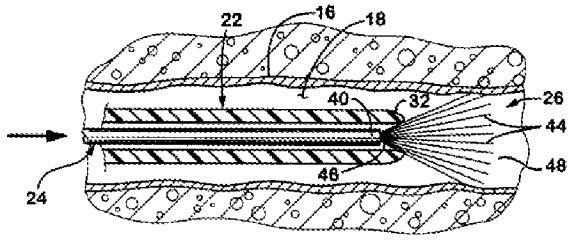


FIG. 3 of Jain

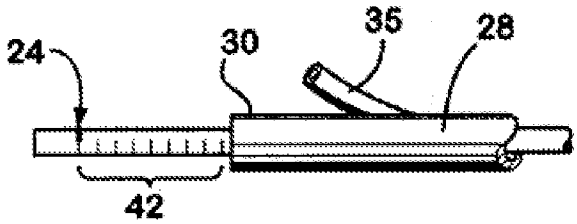


FIG. 4 of Jain

An alternate embodiment of the vascular measuring device in Jain is shown in FIG. 5 (reproduced below), which includes a longitudinal catheter 24 with a sensor 54 at its distal end. The sensor 54 comprises a pair of outwardly-biased arcuate arm springs

56 and 58 joined together at their forward ends and mounted at their rearward ends to the longitudinal rod 50. *See* Jain, column 4, lines 15-22.

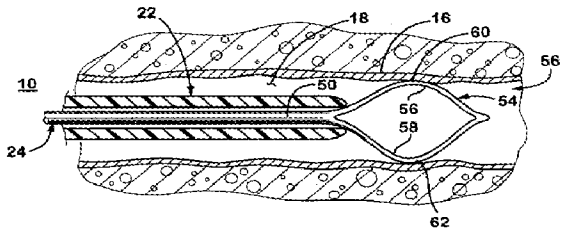


FIG. 5 of in Jain

Colvin

Colvin discloses a body lumen measuring instrument for insertion into a body passageway such as a bronchial tube or the like in order to determine the interior lumen diameter and/or axial length of the passageway at a predetermined location. This instrument can also be used to aid selection of a radioisotope capsule of proper size to be properly positioned at a specific location for tumor treatment. *See* Colvin, Abstract.

As shown in FIG. 5 (reproduced below), probes 54a and 54b merge into a single cable connected to a slide having a corresponding measurement scale for measuring bronchial diameter. Probe 54c is the terminal extension of a second cable connected to a separate slide with a corresponding measurement scale for axial length. *See* Colvin, column 4, lines 1-24.

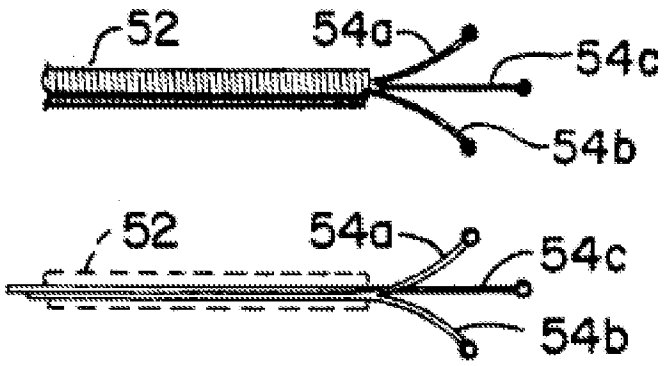
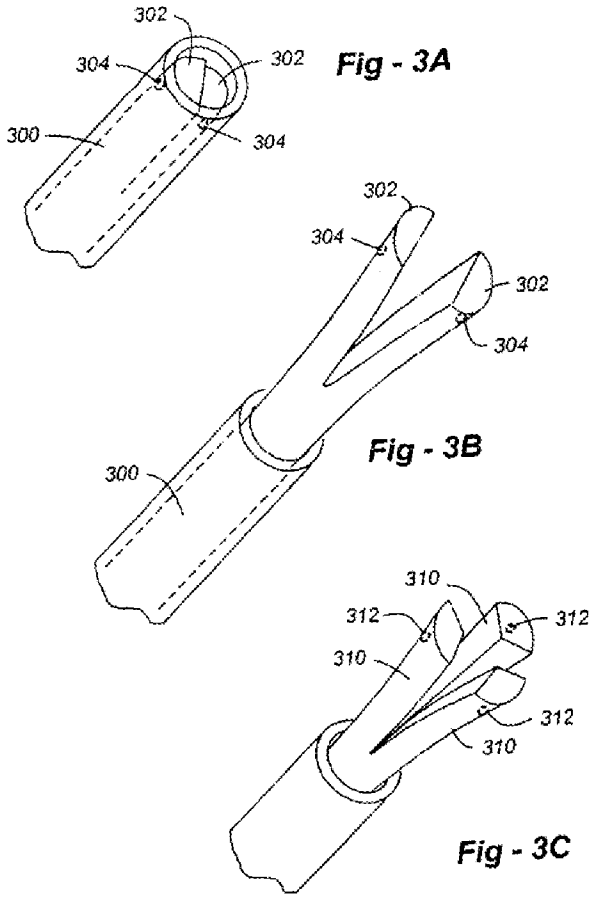


FIG. 5 of Colvin

Haddock

Haddock discloses a thermal sensing catheter for detecting and isolating unstable arterial plaque. *See* Haddock, A*bstract*. As shown in FIGS. 3A-3C (reproduced below), fingers slidingly disposed within an outer sheath 300 are used to place sensors 304 in contact with a surface to be tested. FIG. 3A shows the structure with the fingers 302 and sensors 304 disposed in a retracted position. FIG. 3B shows how the fingers expand when the inner structure is pushed out through the sheath 300, thereby causing the sensors 304 to spread relative to one another so as to contact the inner wall of a vessel. *See* Haddock, column 7, lines 56-64. FIG. 3C shows an embodiment with three fingers, each with a sensor 312. *See* Haddock, column 8, lines 10-13.



Doi

Doi discloses an endoscopic length-measuring tool that passes through a forceps channel to measure a size of a diseased portion within a body cavity. *See* Doi, column 1, lines 6-9. A plurality of splits 3 are formed in a front end portion 1a of a flexible tube 1 of the tool, so as to extend in parallel to an axial direction of the tube 1 and to have equal lengths. Each of the plurality of strips 4 is defined between adjacent splits 3. Radially outwardly bendable portions 5 and 6 and radially inwardly bendable portions 7 are formed on each strip 4. An operating wire 11 is axially and movably disposed within

the tube 1. The front end of the operating wire is retained on a portion of the tube 1 located forwardly from the splits 3. When the operating wire 11 is moved axially and rearwardly relative to the tube 1, the strips 4 are bent at the bendable portions and spread radially outwardly, so that a length-measuring section 9 on the strip 4 is disposed within an observation visual field, which can be observed through an observation optical system (not shown) of an endoscope. *See* Doi, column 2, lines 21-67, column 2, lines 1-53.

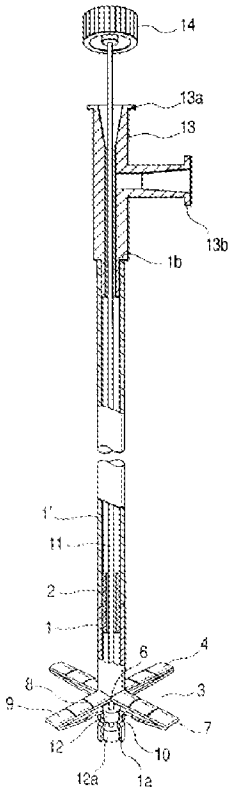


FIG. 1 of Doi

Baxter-Jones

Baxter-Jones discloses a device 1100 for measuring the dimensions of female reproductive organs. *See* Baxter-Jones, Abstract. As shown in FIG. 11 (reproduced below), an elongated member 1102 has a distal region 1106 and a proximal region 1108. A slidable indicator 1116 is slidably engaged on the proximal region 1108. The device further includes a measuring scale 1118 on the proximal region 1108 of the elongated member 1102 that includes a plurality of unidirectional detents 1130. The unidirectional detents 1130 act as locking mechanisms that maintain the position of the slidable indicator 1116 along the measuring scale 1118, after a measurement of a dimension of a female reproductive organ has been taken. *See* Baxter-Jones, column 18 lines 50-67, column 19, lines 1-28.

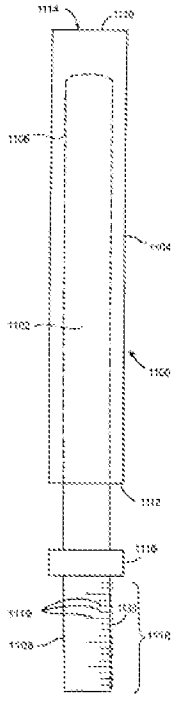


FIG. 11 of Baxter-Jones

In contrast to the disparate devices disclosed in Jain, Colvin, Haddock, Doi, and Baxter-Jones, amended claim 1 recites:

> A device for measuring a target segment of a lumen of a patient so as to select a suitable interventional prosthesis, the device comprising:
>
> an exterior conduit longitudinally extending between proximal and distal ends;
>
> an interior conduit longitudinally extending between proximal and distal ends, disposed within the exterior conduit, and displaceable with respect to the exterior conduit, the interior conduit having a depth marking mechanism visible through a portion of the exterior conduit and configured to provide information regarding a length of the target segment;
>
> a measurement assembly comprising at least two legs having distal and proximal ends and inward facing and lumen facing surfaces wherein the legs are flush with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit, the legs coupled with each other proximal the distal ends thereof, the measurement assembly also coupled about the distal end of the interior conduit, wherein the lumen facing surface of each of the legs includes a plurality of measurement markers, and wherein the exterior conduit is configured to engage the measurement markers of the legs to provide an indication of a diameter of the target segment;
>
> a handle operatively connected with the measurement assembly, the handle comprising a means for opening and closing the measurement assembly by actuating the handle along a continuum between a first closed configuration and a second open configuration.

The Office Action made a large number of disparate rejections, piecing together scattered items of prior art in an attempt to defeat patentability of Applicants' claims. As demonstrated above, not only do those combinations not show or suggest the claimed invention, but there also is no motivation to even try such combinations. The only possible motivation is hindsight reconstruction using Applicants' disclosure as a blueprint.

"[H]indsight-based obvious analysis" has been characterized by the Federal Circuit as a "subtle but powerful attraction." *In re Dembizcak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999), limited on other grounds by *In re Gartside*, 203 F.3d 1305, 53 USPQ2d 1769 (Fed. Cir. 2000). "When the art in question is relatively simple, as is the case here, the opportunity to judge by hindsight is particularly tempting." *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1351, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001). Nevertheless, one "'cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.'" *Ecolochem, Inc. v. Southern California Edison Co.*, 227 F.3d 1361, 1371, 56 USPQ2d 1065, 1072, rehearing denied, suggestion for rehearing en banc declined (Fed. Cir. 2000) citing *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988).

"The genius of invention is often a combination of known elements which in hindsight seems preordained." *McGinley*, 262 F.3d at 1351, 60 USPQ2d at 1008. However, such temptations should be avoided. "[T]hat which only the inventor taught" should not be "used against its teacher." *Id.*

Viewed in this light, the present invention – and the combinations of scattered references – are far from obvious.

There is nothing in Jain, Colvin, Haddock, Doi, or Baxter-Jones, whether alone or in combination, that teach the limitations of claim 1, such as an interior conduit having a depth marking mechanism visible through a portion of the exterior conduit and configured to provide information regarding a length of the target segment, and a measurement assembly comprising at least two legs having distal and proximal ends and inward facing and lumen facing surfaces wherein the legs are flush with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit, the legs coupled with each other proximal the distal ends thereof, the measurement assembly also coupled about the distal end of the interior conduit, wherein the lumen facing surface of each of the legs includes a plurality of measurement markers, and wherein the exterior conduit is configured to engage the measurement markers of the legs to provide an indication of a diameter of the target segment. Consequently, the skilled artisan would not be led to predictably modify Jain, Colvin, Haddock, Doi, or Baxter-Jones in the manner claimed. Therefore, the combination of Jain in view of Colvin, Haddock, Doi, or Baxter-Jones, as proposed in the Office Action, fails to establish a *prima facie* case of obviousness. The Applicant thus respectfully requests that the rejection of claim 1 under 35 U.S.C. § 103(a) be withdrawn.

Claims 3-6, 40, 45, and 46

Each of claims 3-6, 40, 45, and 46 depends from claim 1, either directly or indirectly, and thus includes all the limitations of claim 1. Therefore, for at least the

reasons discussed above with respect to claim 1, the combination of Jain in view of Colvin, Haddock, Doi, or Baxter-Jones, as proposed in the Office Action, fails to establish a *prima facie* case of obviousness. The Applicant thus respectfully requests that the rejection of claims 3-6, 40, 45, and 46 under 35 U.S.C. § 103(a) be withdrawn.

Claim 7

Amended claim 7 recites:

> A method of measuring a target segment of a lumen of a patient so as to select a suitable interventional prosthesis, the method comprising:
>
> providing a measuring device having an exterior conduit longitudinally extending between proximal and distal ends; an interior conduit longitudinally extending between proximal and distal ends, disposed within the exterior conduit, and displaceable with respect to the exterior conduit, the interior conduit having a depth marking mechanism visible through a portion of the exterior conduit and configured to provide information regarding a length of the target segment; a measurement assembly comprising at least two legs having distal and proximal ends and inward facing and lumen facing surfaces wherein the legs are flush with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit, the legs coupled with each other proximal the distal ends thereof, the measurement assembly also coupled about the distal end of the interior conduit, wherein the lumen facing surface of each of the legs includes a plurality of measurement markers that are configured to provide information regarding a diameter of the target segment; a handle operatively connected with the measurement assembly, the handle comprising a means for opening and closing the measurement assembly by actuating the handle along a continuum between a first closed configuration and a second open configuration;
>
> introducing the device into an appropriate anatomical orifice of a patient;
>
> delivering the device adjacent to target segment of a lumen within the patient;

> opening the measurement assembly proximal to and distal to the target segment and noting positions on the depth marking mechanism relative to proximal and distal ends of the target segment;
>
> measuring the distance between the positions on the depth marking mechanism relative to the proximal and distal ends of the target segment to determine the length of the target segment of the lumen within the patient; and
>
> displacing the exterior conduit and measurement assembly relative to one another such that the exterior conduit engages the measurement markers of the legs to provide an indication of a diameter of the target segment.

There is nothing in Jain, Colvin, Haddock, Doi, or Baxter-Jones, whether alone or in combination, that teach the limitations of claim 7, similar to the reasons set forth above with respect to independent claim 1, as well as the steps of delivering the device adjacent to target segment of a lumen within the patient, opening the measurement assembly proximal to and distal to the target segment, noting positions on the depth marking mechanism relative to proximal and distal ends of the target segment, and measuring the distance between the positions on the depth marking mechanism relative to the proximal and distal ends of the target segment to determine the length of the target segment of the lumen within the patient. Consequently, the skilled artisan would not be led to predictably modify Jain, Colvin, Haddock, Doi, or Baxter-Jones in the manner claimed. Therefore, the combination of Jain in view of Colvin, Haddock, Doi, or Baxter-Jones, as proposed in the Office Action, fails to establish a *prima facie* case of obviousness. The Applicant thus respectfully requests that the rejection of claim 7 under 35 U.S.C. § 103(a) be withdrawn.

Claims 8, 10-23, and 48-50

Each of claims 8, 10-23, and 48-50 depends from claim 7, either directly or indirectly, and thus includes all the limitations of claim 7. Therefore, for at least the reasons discussed above with respect to claim 7, the combination of Jain in view of Colvin, Haddock, Doi, or Baxter-Jones, as proposed in the Office Action, fails to establish a *prima facie* case of obviousness. The Applicant thus respectfully requests that the rejection of claims 8, 10-23, and 48-50 under 35 U.S.C. § 103(a) be withdrawn.

Claim 24

Similar to the reasons set forth above with respect to independent claim 7, the Applicants respectfully submits that claim 24 is not anticipated by Jain, Colvin, Haddock, Doi, or Baxter-Jones, whether alone or in combination, and thus request that the rejection of this claim under 35 U.S.C. § 103(a) be withdrawn.

Claims 52-54

Each of claims 52-54 depends from claim 24, either directly or indirectly, and thus includes all the limitations of claim 24. Therefore, for at least the reasons discussed above with respect to claim 24, the combination of Jain in view of Colvin, Haddock, Doi, or Baxter-Jones, as proposed in the Office Action, fails to establish a *prima facie* case of obviousness. The Applicant thus respectfully requests that the rejection of claims 52-54 under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

Applicants respectfully assert that claims 1, 3-8, 10-24, 40, 45-46, 48-50, and 52-54 are patentably distinct from the cited references, and request that a timely Notice of Allowance be issued in this case. If there are any remaining issues preventing allowance of the pending claims that may be clarified by telephone, the Examiner is requested to call the undersigned.

Respectfully submitted,

/Matthew S. Bethards/

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Matthew S. Bethards
Reg. No. 51,466
Attorney for Applicants

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STOEL RIVES LLP
One Utah Center
201 South Main Street, Suite 1100
Salt Lake City, UT 84111
Telephone: (801) 578-6992
Facsimile: (801) 578-6999